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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MARTINEZ, BRITTANY M

ART UNIT	PAPER NUMBER
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1709

MAIL DATE	DELIVERY MODE
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09/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/687,826

Applicant(s)

JACKSON, MARK ALAN

Examiner

Brittany M. Martinez

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 13-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Citation to the Specification will be in the following format (S. #,L) where # denotes the page number and L denotes the paragraph number. Citation to patent literature will be in the format (Inventor #, LL) where # is the column number and LL is the line number.

Priority

Acknowledgment is made of Applicant's claim for priority to U.S. Provisional Application No. 60/429,325, filed November 27, 2002 and U.S. Provisional Application No. 60/421,564, filed October 28, 2002.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12, drawn to a method of providing a manufacturing facility for producing a radioactive material, classified in class 250, subclass 492.3.
 - II. Claims 13-18, drawn to a method of receiving a manufacturing facility for producing a radioactive material at a site, classified in class 250, subclass 492.3.
 - III. Claim 19, drawn to a method of leasing a transportable radiopharmaceutical manufacturing facility, classified in class 705, subclass 13.
 - IV. Claims 20-28, drawn to a transportable manufacturing facility for manufacturing a radiopharmaceutical, classified in class 313, subclass 62.

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2. Inventions I and II are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different function and effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

3. Inventions I and III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different mode of operation and function. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

4. Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case an alternative method of providing a transportable manufacturing facility would be to build the facility on site.

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5. Inventions II and III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different effect. The manufacturing facility being received could be purchased instead of leased. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

6. Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the inventions are distinct because the cyclotron of Invention IV need not be removed. Thus the facility can be built by a process which does not remove the cyclotron.

7. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the

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inventions are distinct because the manufacturing facility could be purchased instead of leased.

Restriction for examination purposes as indicated is proper because all the inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. During a telephone conversation with Tyler Maddry on August 2, 2007 a provisional election was made with traverse to prosecute Invention I, Claims 1-12, drawn to a method of providing a manufacturing facility for producing a radioactive material. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

9. The disclosure is objected to because of the following informalities: Applicant discloses vertical orientation of the cyclotron as optimal for transportability of the facility due to the associated reduced cross sectional area of the cyclotron on the facility floor. However, the applicant contradicts this teaching when disclosing the possibility of the horizontal orientation of the cyclotron (S. 4-5, 0020). In "Background of the Invention" (S. 1,0002), it appears as if "MRI" should replace "MR." The "," after medicine (S. 1, 0003) is unnecessary. It appears that "water" following "¹⁵O" (S. 1, 0004) should be replaced with "aqueous" or "H₂O." The "," following "expensive" (S. 2, 0006) should be replaced with ";". In "Brief Description of the Drawings" (S. 3, 0012), it appears as if "of" should be inserted following "drawing." In "Detailed Description of the Invention" (S. 3, 0015), "radio isotope [*sic*]" is misspelled. The "110" referencing the manufacturing facility (S. 3, 0015) should be "100." The "they" following "when" (S. 4, 0019) appears as if it should be replaced by "the." It appears that "water" following "¹⁵O" (S. 4, 0019) should be replaced with "aqueous" or "H₂O." It appears as if "blow" preceding "flow" (S. 4, 0019) should be replaced with "blood." It appears as if "radio isotope [*sic*]" (S. 6, 0024) is misspelled. The "radiopharmaceutical [*sic*]" following "other" (S. 7, 0032) should be plural. "Nucleophilic" and "Electrophilic" (S. 7, 0032) do not need to be capitalized. The "apparatus" following "supporting" (S. 7, 0033) should be plural. It appears as if "(Radio-TLD) [*sic*]" should actually be "(Radio-TLC)." In general, it appears as if the application was not proofread. Much of the specification lacks antecedent

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basis and uses indefinite language. *Applicants are strongly encouraged to review the entire application for these mistakes and spelling and grammar errors.* Appropriate correction is required.

10. The use of the trademarks MINltrace™, TRACERLab™, and Kryptofix 222™ have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "104" and "135" have both been used to designate a computer. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

11. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. **Claims 1-3 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602) in view of Bergstrom et al. (US 6,445,146) and Wilson et al. (US 4,943,781).

With respect to Claim 1, Dabiri teaches a transportable radioisotope production facility that produces radioisotopes having application to Positron Emission Tomography (PET) (Dabiri, Claims 1, 4, and 13). As to Claims 2-3, Dabiri discloses a radioisotope production facility with a "...radiopharmaceutical subsystem that prepares suitable radiopharmaceuticals from precursors containing the radioisotopes" produced via a particle accelerator (Dabiri, "Abstract", limitations c-d of Claim 13, and Fig. 1). As to Claim 5, Dabiri teaches a method for producing radiopharmaceuticals suitable for use with a PET system (Dabiri, 4, 3-5). Dabiri does not disclose a cyclotron; however, a radio frequency quadrupole (RFQ) linear accelerator is taught as the particle accelerator of choice because typical cyclotrons are too massive for the restricted space available in a transportable radioisotope production facility (Dabiri, 4, 3-5). Bergstrom discloses a compact cyclotron (MINItrace™) suitable for installation in a PET isotope production facility with limited space (Bergstrom, 2, 64-67, and 3,1-5). Wilson further discloses a "highly transportable" cyclotron with reduced size and weight due to lack of iron yoke for the magnet (Wilson, "Abstract"). A person of ordinary skill in the art would recognize from the teachings of Dabiri that cyclotrons are more typically used in PET isotope production systems over RFQ linear accelerators (Dabiri, 1, 59-68, and 2, 1-4), when Dabiri is modified in view of Bergstrom and Wilson, One would have been motivated to

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make such modifications because the space limitations presented by an ordinary cyclotron in a transportable facility (Dabiri, 2, 49-68) could be overcome by a more compact cyclotron (Bergstrom, 2, 64-67, and 3, 1-5 and 60-65).

Claims 1-2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602), Bergstrom et al. (US 6,445,146), and Wilson et al. (US 4,943,781) in view of Applicant's own disclosure.

With respect to Claims 1-2 and 4, to the extent Claims 1-2 and 4 repeat prior limitations, the preceding discussion is incorporated by reference. Dabiri further teaches the production of an ^{18}F isotope via an acceleration system (Dabiri, "Abstract"), but does not explicitly teach the production of a 2- ^{18}F -fluoro-2-deoxyglucose radiopharmaceutical from the ^{18}F isotope via the radiopharmaceutical synthesis subsystem. In Applicant's own disclosure, Applicant has admitted "... ^{18}F is commonly converted to ^{18}FDG (2- ^{18}F -fluoro-2-deoxyglucose)..." (S. 5, 0024). Applicant also cites K. Hamacher, H.H. Coenen and G. Stocklin, J. Nucl. Med. 27, 235-238 (1986) for further details regarding "Additional details of this well known process..." (S. 6, 0031). This art teaches that "In conjunction with positron emission tomography (PET), 2- ^{18}F -fluoro-2-deoxy-D-glucose (2-FDG) is presently the most important radiopharmaceutical..." (K. Hamacher, H.H. Coenen and G. Stocklin, J. Nucl. Med. 27, 235 (1986)). A person of ordinary skill in the art would recognize from the teachings of Dabiri that the "suitable radiopharmaceutical" produced from the ^{18}F isotope obtained via an acceleration system such as a cyclotron system would be a variation of ^{18}F -fluorodeoxyglucose (Dabiri, "Abstract" and Goodman, 2, 14-16).

Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602), Bergstrom et al. (US 6,445,146), and Wilson et al. (US 4,943,781) in view of Wiberg et al. (US 6,392,246).

With respect to Claims 1 and 7, to the extent Claims 1 and 7 repeat prior limitations, the preceding discussion is incorporated by reference. Dabiri does not teach a radiation shielded manufacturing facility because the RFQ linear accelerator taught does not necessitate shielding (Dabiri, 4, 48-53). Wiberg discloses an integrated radiation shield for a PET isotope production system containing a cyclotron (Wiberg, "Abstract"). Further, the compact cyclotron taught by Bergstrom includes an integrated radiation shield for a PET isotope production system (Bergstrom, 2, 64-67, 3, 1-5 and 65-67, and 4, 1-2). A person of ordinary skill in the art would recognize that substituting a cyclotron for the RFQ linear accelerator taught by Dabiri would necessitate integration of radiation shielding similar to that taught by Wiberg or Bergstrom into the transportable radioisotope manufacturing facility.

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602), Bergstrom et al. (US 6,445,146), and Wilson et al. (US 4,943,781) in view of Strawson (US 6,437,344).

With respect to Claims 1 and 8, to the extent Claims 1 and 8 repeat prior limitations, the preceding discussion is incorporated by reference. Dabiri does not teach a radiation shielded manufacturing facility because the RFQ linear accelerator taught does not necessitate shielding (Dabiri, 4, 48-53). Strawson discloses that although the facility may be entirely self-contained, the device may be shipped as two or more

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subassemblies and reassembled on site (Strawson, 31, 53-55). It would be obvious to a person of ordinary skill in the art to install radiation shielding in the walls of the facility post transportation if this would ease transportation to the site or if this was a result of increased shielding requirement regulations at the site.

15. **Claims 1-2, 6, and 9-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602), Bergstrom et al. (US 6,445,146), and Wilson et al. (US 4,943,781) in view of Ashley et al. (US 4,428,908), Zhu et al. (US 5,927,351), and Armel (US 3,411,002).

With respect to Claims 1-2, 6, and 9-11, to the extent Claims 1-2, 6, and 9-11 repeat prior limitations, the preceding discussion is incorporated by reference. With respect to Claims 6 and 10, Dabiri generally discloses an entirely transportable system (Dabiri, Claim 4). Dabiri does not specifically teach packaging or containment equipment to be used with the radiopharmaceuticals produced in the transportable facility. Armel teaches the use of on-site containers for radioactive materials as associated equipment in the completely self-contained unit (Armel, 2, 18-30). Zhu discloses that radiopharmaceuticals utilized in PET systems are typically very radioactive and necessitate heavily shielded transport containers (Zhu, 1, 53-67). A person of ordinary skill in the art would recognize the necessity for specialty packaging/containment as taught by Zhu, and realize that if a facility is entirely transportable and self-contained as disclosed by Dabiri and Armel, respectively, the manufacturing facility would have to be equipped with the packaging equipment and associated packaging room prior to transporting the facility to its designated site (Dabiri,

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Claim 4, Armel, 2, 18-30, and Zhu 1, 53-67). With respect to Claim 9, Dabiri does not teach equipping the manufacturing facility with quality control equipment. Ashley discloses impurities in radiopharmaceuticals are well known in the art, and the presence of such impurities increases radiation doses to non-target organs and contributes to poor quality clinical images when used in nuclear medicine (Ashley, 1, 15-24). Ashley further teaches the "...invaluable benefit in instituting a program of quality control" (Ashley, 1, 15-24). A person of ordinary skill in the art would recognize that equipping the transportable manufacturing facility with quality control equipment as taught by Ashley would be obvious. With respect to Claim 11, Dabiri implies a communications port through the disclosure of a technician-initiated control subsystem that provides control signals for automatic operation of the particle accelerator and targetry (Dabiri, 6, 18-27). Dabiri further teaches a production process support system monitored and controlled by a technician (Dabiri, 14, 36-56, and Claim 10). Where Dabiri does not explicitly teach a communications port connected to at least one sensor on the cyclotron, Bergstrom teaches a feedback system-controlled radio frequency (RF) generation system and a cyclotron controller system for control of "...the electromagnetic field in relation to the accelerating RF field frequency for creating the optimum operation conditions for the created beam of negative hydrogen ions" (Bergstrom, 6, 32-35). A cyclotron control system would be necessary for communication with the cyclotron enclosed in the manufacturing facility.

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Claims 1-3 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602), Bergstrom et al. (US 6,445,146), and Wilson et al. (US 4,943,781) in view of Wiberg et al. (US 6,392,246) and Zhu et al. (US 5,927,351).

With respect to Claims 1-3 and 12, to the extent Claims 1-3 and 12 repeat prior limitations, the preceding discussion is incorporated by reference. Dabiri does not disclose that the manufacturing facility must "satisfy all legal and regulatory requirements of the jurisdiction in which the site is located" (Claim 12 of instant). Wiberg teaches that all radiation hazard regulations have to be followed for PET isotope production systems (Wiberg, 1, 18-21). Zhu teaches further that radiopharmaceuticals should be handled according to U.S. Department of Transportation, Nuclear Regulatory Commission, and Occupational Health and Safety Administration regulations (Zhu, 1, 21-27). It would be obvious to a person of ordinary skill in the art to ensure that the manufacturing facility complied with all legal and regulatory requirements of the jurisdiction in which the site is located, as taught by Wiberg and Zhu.

Conclusion

1. No claim is allowed.
2. All pending claims are subject to restriction requirement.
3. Applicant provisionally elected Invention I, Claims 1-12, with traverse for prosecution.
4. Claims 13-28 are withdrawn from further consideration by the examiner.
5. In general, prior art renders the claimed invention obvious.

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6. Applicant is required to provide pinpoint citation to the specification (i.e. page and paragraph number) to support any amendments to the claims in all subsequent communication with the examiner. **No new matter will be allowed.** The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure.

Applicant's IDS is considered pertinent.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brittany M. Martinez whose telephone number is (571) 270-3586. The examiner can normally be reached Monday-Thursday 6:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VICKIE KIM
PRIMARY EXAMINER

